

ONE HUNDRED FIFTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
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**MEMORANDUM**

**July 23, 2018**

**To: Subcommittee on Health Democratic Members and Staff**  
**Fr: Committee on Energy and Commerce Democratic Staff**  
**Re: Hearing on “21st Century Cures Implementation: Updates from FDA and NIH”**

On **Wednesday, July 25, 2018, at 9:00 a.m., in room 2123 of the Rayburn House Office Building**, the Subcommittee will hold a hearing titled “21st Century Cures Implementation: Updates from FDA and NIH.”

**I. THE 21<sup>st</sup> CENTURY CURES ACT**

The bipartisan 21<sup>st</sup> Century Cures Act (Cures Act) was signed into law on December 13, 2016.<sup>1</sup> The law consists of three divisions: Division A – 21<sup>st</sup> Century Cures Act; Division B – Helping Families in Mental Health Crisis; and Division C – Increasing Choice, Access, and Quality in Health Care for Americans. The purpose of the hearing is to discuss the status of Division A provisions being implemented by the Food and Drug Administration (FDA) and the National Institutes of Health (NIH). These provisions aim to advance the discovery and development of new treatments and cures through increased research and an improved drug approval process. Please refer to the [bipartisan summary](#) of the 21<sup>st</sup> Century Cures Act for more

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<sup>1</sup> Pub. L. No. 114-255.

information on each section of the law.<sup>2</sup> On November 30, 2017 the Subcommittee on Health held a [hearing](#) on Cures Act implementation at FDA and NIH.<sup>3</sup>

### **A. FDA Provisions**

The Cures Act provided FDA with \$500 million in new funding over ten years to foster innovation and to help implement certain provisions in Title III of the bill. These provisions aim to improve FDA's medical product review process and expedite patient access to drugs and medical devices while maintaining the same standards for safety and effectiveness. The law also grants FDA added authority to develop and utilize new tools to facilitate drug development, provide for flexibility in the clinical trial process, encourage the development of regenerative medicine and combination products, and improve FDA's ability to recruit and retain scientific and technical personnel. FDA's [work plan](#) for 21<sup>st</sup> Century Cures outlines the agency's implementation activities.<sup>4</sup>

FDA has made progress on several Cures Act [deliverables](#).<sup>5</sup> For example, in June 2018, FDA released draft guidance on the Limited Population Pathway for Antibacterial and Antifungal Drugs as required by Section 3042 of the Cures Act<sup>6</sup>; a report to Congress on workforce planning and workforce needs at FDA as required by Section 3072<sup>7</sup>; and a list of proposed alternative or streamlined mechanisms for complying with the current good

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<sup>2</sup> Summary of the 21<sup>st</sup> Century Cures Act prepared by bipartisan Committee staff (<https://rules.house.gov/sites/republicans.rules.house.gov/files/114/PDF/114-SAHR34-Sxs.pdf>); See also Congressional Research Service, *The 21st Century Cures Act, Division A of P.L. 114-255* (Dec. 23, 2016) (<http://www.crs.gov/Reports/R44720?source=search&guid=7b425d8813284929a0dd74dbc7947b80&index=0>).

<sup>3</sup> House Committee on Energy and Commerce, *Implementing the 21st Century Cures Act: An Update from FDA and NIH*, 115<sup>th</sup> Cong. (Nov. 30, 2017) (<https://democrats-energycommerce.house.gov/committee-activity/hearings/hearing-on-implementing-the-21st-century-cures-act-an-update-from-fda>).

<sup>4</sup> FDA, *Proposed FDA Work Plan for 21<sup>st</sup> Century Cures Act Innovation Account Activities* (<https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/UCM556618.pdf>).

<sup>5</sup> FDA, *21st Century Cures Act Deliverables* (<https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAAct/21stCenturyCuresAct/ucm562475.htm>).

<sup>6</sup> FDA, *Limited Population Pathway for Antibacterial and Antifungal Drugs, Guidance for Industry* (June 2018) (<https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm610498.pdf>).

<sup>7</sup> FDA, *FDA 21st Century Cures Workforce Planning Report to Congress* (June 2018) (<https://www.fda.gov/downloads/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAAct/21stCenturyCuresAct/UCM612023.pdf>).

manufacturing practice (CGMP) requirements for combination products as required by Section 3038.<sup>8</sup>

## **B. NIH Provisions**

The Cures Act provided NIH with \$4.8 billion in new funding to advance several cutting edge research initiatives including: \$1.8 billion in funding to support the Beau Biden Cancer Moonshot Initiative which aims to accelerate cancer research and improve our ability to prevent and detect early-stage cancers; \$1.5 billion in funding for the Obama Administration's Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative to help discover new ways to treat, cure, and prevent brain disorders such as Alzheimer's, epilepsy and traumatic brain injury; \$1.45 billion in funding for former President Obama's Precision Medicine Initiative (PMI), which seeks to help researchers develop medicines tailored to individuals, rather than one-size-fits-all treatments; and \$30 million in funding for the Regenerative Medicine Innovation Project to support clinical research to advance the field of regenerative medicine.<sup>9</sup>

In May 2018, NIH opened nationwide enrollment for the *All of Us* Research Program (formerly known as the PMI Cohort Program). *All of Us* aims to enroll a diverse research cohort of one million or more individuals. The program has formed partnerships with providers and community organizations to bolster study recruitment activities, particularly the recruitment of those historically underrepresented in biomedical research.

## **II. WITNESSES**

The following witnesses have been invited to testify. Dr. Devaney and Dr. Sharpless will not provide official testimony but will be present to answer questions.

**Scott Gottlieb, M.D.**

Commissioner

U.S. Food and Drug Administration

**Francis S. Collins, M.D., Ph.D.**

Director

National Institutes of Health

**Stephanie Devaney, Ph.D.**

Deputy Director

All of Us Research Program

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<sup>8</sup> FDA, *Alternative or Streamlined Mechanisms for Complying With the Current Good Manufacturing Practice Requirements for Combination Products; Proposed List Under the 21st Century Cures Act* (June 13, 2018) (<https://www.federalregister.gov/documents/2018/06/13/2018-12634/alternative-or-streamlined-mechanisms-for-complying-with-the-current-good-manufacturing-practice>).

<sup>9</sup> NIH, *The 21st Century Cures Act* (<https://www.nih.gov/research-training/medical-research-initiatives/cures>).

National Institutes of Health

**Norman Sharpless, M.D.**

Director

National Cancer Institute

National Institutes of Health